

## **ATTACHMENT B**

### **Massachusetts Department of Public Health**

#### **DRAFT Guidelines Authorizing Pharmacists, Dentists and Certified EMT-Paramedics to Administer Immunization Vaccines Against Seasonal Influenza and Pandemic Influenza A H1N1 2009**

**Effective Date: XXX**

##### **A. Purpose**

In preparation for pandemic H1N1 2009 influenza, the Massachusetts Public Health Council recently approved emergency amendments to 105 CMR 700.000, regulations governing the implementation of the Controlled Substances Act, M.G.L. c.94C. The emergency regulations were filed with the Secretary of the Commonwealth on September **XX**, 2009 and became effective on that date. The aim is to expedite the administration of influenza vaccines so that large numbers of people can be vaccinated in a short period of time.

The emergency amendments allow the Commissioner of the Massachusetts Department of Public Health (the Commissioner) to expand the type and number of health care professionals who may administer influenza vaccines, but do not require members of these professions to participate in the administration of vaccines. Specifically, the emergency amendments allow the Commissioner to authorize health care professionals licensed or certified by the Massachusetts Department of Public Health (MDPH) to administer vaccine for the prevention of influenza, provided the Commissioner determines that there are, or will be, insufficient numbers of currently authorized health care professionals available for timely vaccine administration. The Commissioner must issue an order authorizing such vaccine administration and specify certain parameters of vaccine administration.

The approved amendments require a health care professional administering vaccine to be properly trained and supervised. In addition, the regulations require that the vaccine be administered under an order or prescription of a practitioner authorized to prescribe vaccines. The person administering must comply with the order of the Commissioner and the prescriber's order with respect to proper storage, handling and return of the vaccines, record keeping of administration, responses to adverse events, and safe and appropriate administration of vaccines. Health professionals who are responsible for overseeing immunization clinics have the right to determine which individuals they will allow to administer vaccines in their clinic and may require vaccinators to have additional training or competency evaluation (e.g., just-in-time), beyond what is described in these guidelines, to assure the safe, appropriate and effective administration of influenza vaccine in their clinic. This document outlines:

- Requirements for the authorization, training and professional documentation that must be maintained by health care professionals (pharmacists, dentists, EMT-paramedics) who may administer vaccine under the Commissioner's Order;
- Required elements of vaccine administration training programs for the targeted health care professionals;

- Documentation requirements for training programs on influenza vaccine administration;
- Documentation that must be issued and available to verify the successful completion of required training by targeted health care professionals; and
- Information and links to the MDPH's written protocols covering the latest guidance and requirements about vaccine ordering, storage, provision of information and documentation.

## B. Authorization, Training and Documentation Requirements for Health Care Professionals

The following guidelines specify the standards that licensed pharmacists and dentists, and certified EMT-paramedics must satisfy in order to administer vaccine for the prevention of influenza pursuant to the Commissioner's Order number **XXX**. Health professionals who are responsible for overseeing immunization clinics have the right to determine which individuals they will allow to administer vaccines in their clinic and may require vaccinators to have additional training or competency evaluation (e.g., just-in-time), beyond what is described in these guidelines, to assure the safe, appropriate and effective administration of influenza vaccine in their clinic.

### Pharmacists

**Commissioner's Authorization:** Since 2000, pharmacists who have undergone training according to a curriculum approved by MDPH and Massachusetts Board of Registration in Pharmacy have been authorized to administer influenza vaccine and certain other vaccines to persons 18 years old or older. Specific authorization in the Commissioner's Order authorizes, but does not require, a pharmacist to administer vaccine **to persons 12 years old or older** for the prevention of influenza under an order or prescription of a practitioner authorized to prescribe provided that the pharmacist:

- 1) is in good standing<sup>1</sup> with and currently licensed by the Massachusetts Board of Registration in Pharmacy to practice pharmacy in Massachusetts;
- 2) has successfully completed an education program accredited by the Centers for Disease Control and Prevention, the Accreditation Council for Pharmacy Education (ACPE) or a similar health authority or professional body, in accordance with 105 CMR 700.004, the Board of Registration in Pharmacy or vaccination training program sponsored by MDPH on the safe, appropriate and effective administration of influenza vaccine and demonstrated competence to administer vaccines upon completion of that training;
- 3) maintains official documentation of successful completion of required training which has been issued by the training program/sponsor; and
- 4) is prepared to present such documentation as well as his/her license to practice pharmacy in the Commonwealth upon request of the MDPH, the Board of Registration in Pharmacy, a patient/person who is being vaccinated by the pharmacist, or from an administrator/health professional who is responsible for determining the qualifications of a pharmacist who wishes to administer vaccinations as part of a vaccine administration program or clinic.

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<sup>1</sup> A license or certification that is in good standing is current and not on disciplinary status of probation, suspension, or revocation.

## **EMT-Paramedics**

**Commissioner's Authorization:** EMT-Paramedics are currently authorized to administer certain medications intravenously, intramuscularly and subcutaneously under the Department's EMS System regulations and Statewide Treatment Protocols of the MDPH Office of Emergency Medical Services (OEMS) and under the supervision of a medical director. They are also trained in accordance with the U. S. Department of Transportation's EMT-Paramedic National Standard Curriculum to administer such medications. Specific authorization in the Commissioner's Order authorizes, but does not require, an EMT-Paramedic certified by OEMS to administer vaccine for the prevention of influenza in accordance with OEMS protocols issued for this purpose and under the supervision of the medical director of the Massachusetts licensed ambulance service with which they work, provided that the EMT-Paramedic:

- 1) is in good standing<sup>1</sup> with and currently certified by the MDPH Office of Emergency Medical Services at the EMT-Paramedic level;
- 2) has successfully completed a training program provided by his/her ambulance service, under the oversight of his/her medical director and based on training standards provided by OEMS or a vaccination training program sponsored by MDPH on the safe, appropriate and effective administration of influenza vaccine, and where the medical director has determined that the EMT-Paramedic has demonstrated competence to administer vaccines upon completion of that training;
- 3) maintains official documentation of successful completion of required training which has been issued by his/her ambulance service; and
- 4) is prepared to present such documentation as well as his/her EMT-Paramedic certification issued by OEMS upon request of the MDPH, a patient/person who is being vaccinated by the EMT-Paramedic, or from an administrator/health professional who is responsible for determining the qualifications of an EMT-Paramedic who wishes to administer vaccinations under the direction of the ambulance service medical director as part of a vaccine administration program or clinic.

## **Dentists**

**Commissioner's Authorization:** Neither the prescribing nor the administration of vaccines is within the defined scope of practice of dentists licensed to practice dentistry in Massachusetts. However, the Commissioner's Order authorizes, but does not require, a dentist to administer vaccine for the prevention of influenza under an order or prescription of a practitioner authorized to prescribe vaccine provided that the dentist:

- 1) is in good standing<sup>1</sup> with and currently licensed by the Massachusetts Board of Registration in Dentistry to practice dentistry in Massachusetts;
- 2) administers influenza vaccines under the auspices of an immunization program of a licensed health care facility, visiting nurse agency, public health or government agency, accredited/approved dental, pharmacy or medical school, the Massachusetts Dental Society, or other recognized public health or professional organization;
- 3) has successfully completed an education program offered by a licensed health care facility, public health agency, accredited/approved dental, pharmacy or medical school, or sponsored by the MDPH, the Massachusetts Dental Society or other recognized public health or professional organization on the safe, appropriate and effective administration

of influenza vaccine, and demonstrates proficiency in administering vaccines consistent with completion of that training program;

- 4) maintains official documentation of successful completion of required training which has been issued by the training program/sponsor; and
- 5) is prepared to present such documentation as well as his/her license to practice dentistry in the Commonwealth upon request of the MDPH, the Board of Registration in Dentistry, a patient/person who is being vaccinated by the dentist, or from an administrator/health professional who is responsible for determining the qualifications of a dentist who wishes to administer vaccinations as part of a vaccine administration program or clinic.

C. Required Elements of Programs to Train Health Care Professionals in the Safe, Appropriate and Effective Administration of Influenza Vaccines

Curricula for the training of health professionals in the safe, appropriate and effective administration of influenza vaccine shall contain, at a minimum, content pertaining to:

- 1) The nature of immunization and influenza vaccines
- 2) Content of patient education and use of the Vaccine Information Statement (VIS)
- 3) Screening for appropriateness of and contraindications to immunization
- 4) Vaccine storage and handling
- 5) Safe and appropriate administration of injectable and live, attenuated influenza vaccine
- 6) Indications for the evaluation of and response to medical emergencies, and the administration of medications to treat such emergencies
- 7) Recognition and reporting of adverse events
- 8) Record keeping

D. Documentation Requirements for Influenza Vaccine Administration Training Programs

The sponsor of a training program in the safe, appropriate and effective administration of influenza vaccine shall keep the following records for a period of three (3) years. Records shall be furnished to the MDPH upon request.

- 1) Course description
- 2) Faculty
- 3) Date of the training
- 4) Location of the training
- 5) Roster of attendees
- 6) Continuing education credits, if applicable

All participants must be provided with a written certification of successful completion and attendance which includes:

- 1) Name and address of the training organization/sponsor
- 2) Participant's name, address and professional license/certification number
- 3) A brief statement of the subject matter
- 4) Date and location of the training program

- 5) Signature and title of a qualified representative of the training organization attesting to the proficiency of the participant in the safe, appropriate and effective administration of influenza vaccines, injectable and/or nasal administration of influenza vaccine(s)
- 6) Number of continuing education credits issued, if applicable

#### E. Written Protocols

The Department's written clinic protocols covering the latest guidance and requirements about vaccine ordering, storage, provision of information and documentation can be found at <http://www.mass.gov/dph/imm>, and then click on "Vaccine Management." Standing orders for vaccines and clinic protocols can be found by going to <http://www.mass.gov/dph/imm> and clicking on "Model Standing Orders."

Links to a couple of very helpful recommendations are noted below. Additional guidance and other resources for immunization training can also be found on the DPH website.

Prevention and Control of Seasonal Influenza with Vaccines, Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2009 (CDC)  
<http://www.cdc.gov/mmwr/pdf/rr/rr5808.pdf>

Use of Influenza A (H1N1) 2009 Monovalent Vaccine, Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2009 (CDC)  
<http://www.cdc.gov/mmwr/PDF/rr/rr5810.pdf>

Information about upcoming immunization training programs can also be found on the DPH website at <http://www.mass.gov/dph/imm>

#### Latest Information on Influenza Outbreak and Vaccination

There is helpful information about flu vaccine, including the risks and benefits of getting vaccinated, and H1N1 guidance, on the Centers for Disease Control and Prevention's (CDC's) website at <http://www.cdc.gov/flu>. For the latest updates on influenza also please visit the Department's website at [www.mass.gov/dph/flu](http://www.mass.gov/dph/flu).

#### Contact Information

If you have any questions concerning the emergency amendments to 105 CMR 700.000, please contact the Drug Control Program at 617-983-6700 or [dcp.dph@state.ma.us](mailto:dcp.dph@state.ma.us). Questions concerning vaccine administration, training and management should be directed to the Immunization Program at 617-983-6800.